K022764

Section 9

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. **Identifying Information**

(a) Submitters Name:	Medtronic AVE, Inc. 37A Cherry Hill Drive Danvers, MA 01923
(b) Contact Person:	Fred L. Boucher R.A.C. (978) 777-0042
(c) Classification Name:	Percutaneous Catheter (21 CFR Part 870.1250)
(d) Proprietary Name:	Medtronic 7F Launcher Guide Catheter
(e) Name of Predicate Devices	Medtronic® 6F Z3 Guide Catheter - K021256

2. **Description**

The Medtronic Launcher Guide Catheter is constructed with an inner liner, stainless steel braid, outer shaft jacket, sleeve, marker band and a soft distal tip. The inner lumen of the Launcher Guide Catheter has a thin lubricious coating.

3. **Intended Use**

The Medtronic Launcher Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended for used in the coronary or peripheral vascular system.

4. **Technological Characteristics**

The 7F Launcher Guide Catheters are manufactured similar to the legally marketed predicate 6F Z3 Guide Catheters.

The manufacturing processes, materials and design are substantially equivalent to the 6F Z3 Guide Catheter.

5. Biocompatibility tests performed per ISO10993 were chosen based on Guide Catheters categorized as external-communicating devices, circulating blood, limited exposure (≤24 hours). The following test results reports have been received and the results demonstrate that the tests were successfully performed. All materials used for the Medtronic® Launcher Guiding Catheter passed the following tests:

   Acute Intracutaneous Reactivity
   Acute Systemic Toxicity
   Cytotoxicity
   Hemolysis
   Sensitization (Test in process at the time of this submission.)

6. Functional testing consisted of hub to shaft, shaft, distal tip to shaft tensile, torque response, lumen lubricity, radiopacity, pressure shaft burst and hub leak, tip compression (softness). Results verified that the Medtronic® Launcher Guiding Catheter meets all of the applicable specifications and considered an appropriate device for the intended use. Based on a comparison of the intended use, design, in-vitro test results and the fact that the fundamental scientific technology has not changed, the Launcher guide catheter is considered to be substantially equivalent to the following device:

   - Medtronic® 6F Z3 Guiding Catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Medtronic, Inc.
c/o Mr. Fred L. Boucher, R.A.C.
Sr. Regulatory Affairs Manager
37A Cherry Hill Drive
Danvers, MA 01923

Re: K022764
Medtronic® Launcher Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II (two)
Product Code: 74 DQY
Dated: August 20, 2002
Received: August 21, 2002

Dear Mr. Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K022764

Device Name: Medtronic® Launcher Guiding Catheter

Indications for Use: The Medtronic® Launcher Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The Launcher catheter is intended to be used in the coronary or peripheral vascular system.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K022764

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)